

K091047

P. 1/2



LMT Medical Systems GmbH – Osterweide 8 – 23562 Luebeck - Germany

510(k) Summary

AUG 18 2010

Preparation Date:	June, 8 th 2010
Applicant	LMT Medical Systems GmbH Osterweide 8 23562 Luebeck Germany
Establ. Registration No.	
Contact Person:	Thomas Bohnen Tel: +49-451-58098-14 Fax: +49-451-58098-15 Email: bohnens@lammersmedical.com
Proprietary Name	Neonate Head Array Coil (NHAC)
Common Name	Neonate Body Array Coil (NBAC)
Device Panel:	Coil, Magnetic Resonance, Specialty
Product Code	Radiology
Class	MOS 2 (21 CFR 892.1000)
Applicable standards	IEC 60601-2-33 NEMA MS-1 NEMA MS-3 NEMA MS-6 NEMA MS-9
Legally marketed devices	RF Coils, Advanced Imaging Research, Inc. (K023929)
Reason for 510(k):	New device (Traditional)

Intended Use

The Neonate Array Coils are local coils (receive only) and are intended to be used in conjunction with 1.5T or 3.0T magnetic resonance imaging (MRI) systems by Philips or Siemens and can be used in conjunction with the LMT nomag® IC MR-compatible incubator.

They provide MR images of the neonatal head or body, noninvasively without the use of ionizing radiation. When interpreted by a trained physician, these images provide information that can be useful in the determination of a diagnosis. The excited nucleus is 1H (Proton).

Description of the Device

The Neonate Array Coils (in the following NAC) is a phased array coil with rectangle loop design and integrated RF preamp per channel. It is a receive-only coil targeted for horizontal B-field scanners with field strengths of 1.5T or 3.0T.

Design and Specifications

The safety and performance parameters specified by the FDA guidance for MR Diagnostic Devices are met by the NAC.

- | | |
|-------------|-------------------------|
| Performance | - Imaging |
| Safety | - Static Field Strength |
| | - Acoustic Noise |
| | - dB/dt |
| | - RF Heating |
| | - Biocompatibility |

Comparison summary

LMT Medical Systems believes that the following technology characteristics of NAC (LMT) and the above mentioned predicate devices (Advanced Imaging Research, Inc. (K023929)) are substantially equivalent concerning:

- | | |
|--------------------------------|--|
| • Environmental specifications | • Ergonomics of the patient-user interface |
| • Performance specifications | |

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Thomas Bohnen, QM and Regulatory Affairs

LMT Medical Systems GmbH, Germany



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Kristina Luetje
Regulatory Affairs Manager
LMT Medical Systems GmbH
Osterweide 8, Lubeck 23562
GERMANY

AUG 18 2010

Re: K091047
Trade/Device Name: Neonate Array Coils
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: June 16, 2010
Received: June 21, 2010

Dear Ms. Luetje:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

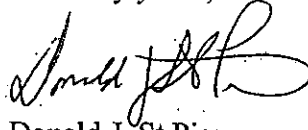
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Donald J. St. Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K091047

Device Name: Neonate Array Coils

Used in a MR Scanner or used in the LMT nomag IC incubator and a MR Scanner, the Neonate Array Coils (receive only) are indicated for use as a diagnostic imaging device to provide transversal, sagittal, coronal and oblique images of the internal structures of the

- head (Neonate Head Array Coil)
- spine, torso (Neonate Body Array Coil).

When interpreted by a trained physician, these images provide information that can be useful in the determination of a diagnosis. The excited nucleus is $1H$ (Proton). The signal received by the coils is dependent upon the MRI parameters (T1 or spin-lattice relaxation time, T2 or spin-spin relaxation time, density of nuclei, flow velocity and chemical shift). The Neonate Array coils are compatible to Siemens and Philips MRTs with 1.5T or 3.0T.

Prescription Use

X

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

OIVD



(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K161373 K091047